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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,880	07/30/2003	Peter Franz Ertl	PG4082-1C1	4955

7590 09/07/2005

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,880	ERTL ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The receipt of preliminary amendment of 7/30/2003 is acknowledged. Claims 1-35 have been canceled. Claims 36-53 have been added and are pending before the examiner.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

A copy of the PCT/GB01/03290 has not been submitted. Applicants are reminded that this is a continuation in part application (CIP). In the absence of certified copies, the examiner can not determine the extent of claimed priority, whether or not applicants had sufficient support for now claimed invention. Hence, the claim priority for the pending application is determined to be the filing date of application no. 09/939,471 filed on 08/24/2001, until such time where applicants provide a certified and translated copy and further pointing to specific pages and paragraphs that lend support for the now claimed invention in the priority application(s).

In addition, acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on 07/21/1997. It is noted, however, that applicant has not filed a certified copy of the GB0017990.3 application as required by 35 U.S.C. 119(b). In addition, a certified translation is requested. The claim priority to

07/20/2000 is hereby denied until such time where certified copies are submitted. Still further, Please up-date the information by inserting the current status of application(s).

Claim Objections

Claims 37 and 38 are objected to because of the following: they are identical of each other; one of the two would be sufficient. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites the limitation "wherein the early protein" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 40 recites the limitation "wherein the polypeptide comprises more than one HPV early protein" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

Claims 36-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for HPV6b E1 and HPV 11 E2 which are codon optimized or modified to be utilized in a n induction of antibody immune response (treatment only), does not reasonably provide enablement for any and all "codon usage pattern" of all HPVs genes which has been rearranged to be expressed treat and/or prevent infection caused by HPVs. The specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification does not provide a credible teaching within the broad scope of claimed invention wherein the "codon usage pattern" is maintained. This field is unpredictable as Applicants' own specification attests. One of ordinary skill in the art would be required to conduct large quantity of undue experimentation to find which sequences that fall within the framework of the claimed invention. The gene shuffling although on the surface seems straightforward, in reality it is not that straightforward absent adequate teaching, and undue experimentation would be required for one ordinary skill in the art to enable the full scope of the claimed invention. There are issues of toxicity, transformation and reversion of rearranged protein to the wild type that should be considered. Applicants have rearranged only papillomavirus sequences namely E1 polynucleotide of HPV6b E1, and HPV11 E2. HPV6 and HPV 11, however, are highly identical and have overlapping regions that are hundred percent identical, as evidence see (Yaegashi et al, Journal of Virology, April 1992, Vol. 66, No. 4, pages 2008-2019). Thus, Applicants in effect have optimized only one papillomavirus type. However, the scope of disclosure does not support for shuffling of all types of HPVs genes or even all genes of HPV6b, HPV11 to be able to be expressed or induce immune response while not transform and/or induce toxicity within the scope of claimed invention. As further evidence in unpredictability of the field and state of the art please see teaching of Osen et al , 2001, Vaccine , Vol. 19, pp. 4276-4286, wherein Osen et al taught the "potential concern" of reversion to wild type of shuffled molecule should be considered (see page 4284, 1st paragraph). Teaching of Osen et al is indicative of unpredictability of the field, it's concluded that the

invention is not enabling within the full scope of the claimed invention at the time of filing, and the specification doses not provide adequate teaching to overcome the concerns. Therefore, with regard to an unpredictable field, this does not constitute an adequate disclosure. Still further, the scope of the claims are directed to vaccines, Applicants have general statements regarding the method of preventing HPV infection. Regarding to an unpredictable field, however, this does not constitute an adequate disclosure. See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for development of method of preventing infection. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The applicant cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. In the instant disclosure, Applicants have only disclosed the optimized sequence of HPV6b E1, HPV11 E2 only. No other sequences, which are "optimized", were disclosed. The specification does not set forth the metes and bounds of that encompasses of "codon usage pattern" of "highly expressed mammalian genes having", and there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed regions. Therefore, a written description of the other sequences that should be utilized in the methods should be disclosed to overcome this rejection. If Applicants were not in the possession of the optimized sequences, then the methods that utilized the sequences also lack written description. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one

skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 19 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36-43, and 47-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Neeper et al (WO 01/14416 A2).

The above cited art taught method of optimizing polynucleotide of HPV gene regions for induction of immune response, and in the process the polypeptide would be expressed in mammalian cells (see the abstract, and claims 26-30). The claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claims 36-43, and 47-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Neeper et al (US20050075303 A1).

The above cited art taught method of optimizing polynucleotide of HPV gene regions for induction of immune response, and in the process the polypeptide would be expressed in mammalian cells (see the abstract, and claims 32-34). The claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 36-43, and 47-50 are rejected under 35 U.S.C. 102(a) as being anticipated by Neeper et al (WO 01/14416 A2).

The above cited art taught method of optimizing polynucleotide of HPV gene regions for induction of immune response, and in the process the polypeptide would be expressed in mammalian cells (see the abstract, and claims 26-30). The claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

8/29/2005

ALI R. SALIMI
PRIMARY EXAMINER